IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO:
ETHICON WAVE 1 CASES

REPLY IN SUPPORT OF THEIR MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF JAIME L. SEPULVEDA-TORO, M.D.

Plaintiffs hereby submit *Reply in Support of Their Motion to Limit the Opinions and Testimony of Jaime L. Sepulveda, M.D.*, and respectfully show the Court as follows:

I. ARGUMENT[1]

In their Opposition, Defendants repeatedly argue that Plaintiffs "distort[] his [Dr. Sepulveda-Toro's] opinions and disregard[] his distinguished qualifications" as well as "mischaracterize" and "misrepresent" Dr. Sepulveda-Toro's opinions, testimony, and the

[1] Defendants' Opposition brief was 23 pages. Even so, Defendants failed to seek or obtain the Court's permission to file an opposition that exceeded the page limit by 3 pages. In PTO No. 217, this Court ordered: "The page limitations provided in Local Rule of Civil Procedure 7.1(a)(2) apply to memoranda in support of all dispositive and *Daubert* motions, oppositions, and replies, and the court will not be inclined to grant motions to exceed the page limit." PTO No. 217(B)(6). Local Rule of Civil Procedure 7.1(a)(2) further provides: "A memorandum of not more than 20 pages in length must accompany the following types of motions: [*Daubert* motions, oppositions, and replies pursuant to PTO No. 217] . . . [m]otions to exceed the page limitation are disfavored and will be denied absent a showing of good cause." L.R. Civ. P. 7.1(a)(2) (underscore added). Further, the local rule states: "Unless extraordinary circumstances exist, a motion to exceed the page limitation . . . must be tendered to the presiding judge at least 3 days in advance" and "[i]f a memorandum is not submitted as required by this rule or by the court, the motion will be denied without prejudice." *Id.* (underscore added). Because Defendants filed an over-length memorandum in opposition, while failing to submit a motion seeking leave to file the same (let alone demonstrating good cause for exceeding the page limit), Defendants' Opposition should be stricken and not considered in deciding Plaintiffs' Motion.

scientific literature. *See e.g.*, Defs.' Opp. at 1-2. This theme, running throughout Defendants' Opposition, stems from Defendants' failure to interpret Dr. Sepulveda-Toro's expert opinions and testimony in a way consistent with their plain meaning. In addition, and often because of Defendants' strained interpretation of Dr. Sepulveda-Toro's opinions and testimony, Defendants' substantive arguments are without merit, and therefore, Plaintiffs' Motion should be granted in its entirety.

A. Dr. Sepulveda-Toro Should Not be Permitted to Opine on Safety and Efficacy.

While Defendants argue that: "Plaintiffs falsely contend that Dr. Sepulveda agrees with the FDA's classification of Gynemesh PS, Prolift, and Prosima as high risk devices," Defs.' Opp. at 4, the fact remains that Dr. Sepulveda-Toro testified that: "I -- I'll -- I agree with the approval the FDA has and I'm not going to challenge the FDA or their panel on that one." Pls.' Mot. at 5. The fact that Dr. Sepulveda-Toro also testified that terms such as "high risk" and "low risk" are "so nonspecific," Defs.' Opp. at 5, does not somehow negate his agreement with the FDA's classification. Indeed, when asked whether he could label surgical mesh used to repair POP issues as high risk, Dr. Sepulveda-Toro testified: "Yeah, it's labeled high risk and there's communication from the FDA labeling it high risk." Ex. E at 250:2-7. Dr. Sepulveda-Toro's actual objection to the terms "high" or "low risk" concern his opinion that they cannot be adequately "explain[ed] in the context of a deposition." *Id.* at 250:24 – 251:1-3. Thus, Defendants' attempt to obfuscate Dr. Sepulveda-Toro's otherwise clear testimony is unavailing.

Next, Defendants assert that Plaintiffs argued in their Motion that Dr. Sepulveda-Toro quit using POP products "for safety reasons." Defs.' Opp. at 5. A clear reading of Plaintiffs' Motion indicates Plaintiffs argued he "admits he no longer uses the POP devices because he cannot." Pls.' Mot. at 5 (underscore added). Defendants simply misconstrue this argument and

eventually agree with Plaintiffs that "Dr. Sepulveda therefore stopped using the devices only after he was forced to." Defs.' Opp. at 6. Defendants also take issue with the fact that Dr. Sepulveda-Toro was unable to name a long-term study on the safety of the TVT-O device. However, Defendants fail to realize that the crux of Plaintiffs' argument is not whether Dr. Sepulveda-Toro successfully passed a "memory test," but rather, that Dr. Sepulveda-Toro's cited studies are in fact outliers. *See* Pl.'s Mot. at 5. Defendants' assertion that Dr. Sepulveda-Toro cites "numerous studies" to show that Defendants' products are "safe and effective" is inconsistent with the fact that Dr. Sepulveda-Toro, admitted in deposition, that the amount of studies noted in his reports, including the conclusions drawn therefrom, is greatly overstated. Pls.' Mot. at 10-12. Moreover, Defendants' characterization of Dr. Sepulveda-Toro's cited studies is inconsistent with the plain language in his expert reports. *See, e.g.*, Defs.' Opp. at 4 (claiming that Dr. Sepulveda-Toro cited "two separate studies on Prosima showing its efficacy and positive safety profile" even though Defendants' citation to the expert report points to a study focused on "clinical outcomes" with no indication whatsoever that efficacy or safety were focuses of these studies).

Because Dr. Sepulveda-Toro agrees with the FDA's classification of Defendants' products as high risk, indeed, he is not allowed to use the POP products, and the number of his cited studies is overstated, including the conclusions drawn therefrom, Dr. Sepulveda-Toro's opinions on safety and efficacy should excluded.

B. Dr. Sepulveda-Toro Should Not be Permitted to Opine on Public Health Notices, IFUs, or Patient Brochures.

First, Defendants argue that Dr. Sepulveda-Toro should be permitted to proffer the opinion that all pelvic floor surgeons "would be aware of" and expected to know of the FDA's 2008 Public Health Notice. Defs.' Opp. at 7-8. However, Defendants point to no bases in Dr.

Sepulveda-Toro's expert report or deposition that separates these opinions from speculation or conjecture. Defendants' rehashing of Dr. Sepulveda-Toro's qualifications, *see* Defs.' Opp. at 7, does not inform on the dispositive question: how does Dr. Sepulveda-Toro know that all pelvic floor surgeons "would be aware of" the 2008 Public Health Notice? It does not, and Dr. Sepulveda-Toro should not be allowed to opine on this subject.

Second, Defendants argue that Dr. Sepulveda-Toro should be allowed to opine on their IFUs and patient brochures because "Dr. Sepulveda's testimony is *not* a legal conclusion." Defs.' Opp. at 8. Defendants then spend much page space arguing about the legal requirements of a failure to warn claim (which is necessarily dependent on the state law applicable to any single case making this argument inapplicable in a general causation *Daubert* motion), Defs.' Opp. at 8-9, and what the IFUs at issue actually stated. Def.'s Opp at 9-10. None of these observations set forth by Defendant are helpful in answering the critical question: Is Dr. Sepulveda-Toro qualified to opine on Defendants' IFUs and patient brochures? Dr. Sepulveda-Toro's expert opinion states: "I have reviewed the IFUs and find them adequate and complete for use in the operating room and by the intended users," and is in fact, a straightforward legal conclusion that the IFUs comply with federal regulations and constitutes exactly the type of expert opinion previously excluded by this Court. *See* Pl.'s Mot. at 7-8 (underscore added); *see also Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 582 (S.D. W. Va. 2014) (excluding Dr. Culligan's opinions on adequacy of defendants' DFU despite fact Dr. Culligan had participated in drafting an unrelated DFU (also excluding Dr. Culligan's opinions on patient brochures for inadequate disclosure of opinion)).[2]

[2] Defendants also elaborate upon Dr. Sepulveda's clinical experience, his experience as an instructor for Ethicon, his review of the medical literature concerning complications of surgery, and his opinion that there are fewer complications involved with mesh surgery as compared to

C. Dr. Sepulveda-Toro Should Not be Permitted to Opine on Product Defects.

Defendants argue that Dr. Sepulveda-Toro is qualified to opine that Defendants' products are not defective even though this Court has previously excluded opinions nearly identical to his, *i.e.*, opinions formed on design defects without expertise in mesh product design or biomaterials. *See id.* at 581 (excluding Dr. Culligan's opinions on design defects where he was not an expert in biomaterials and had never performed product design work). Dr. Sepulveda-Toro's experience, qualifications, and methodology place him squarely in the same category as Dr. Culligan. Defendants' attempts to compare Dr. Sepulveda-Toro to the experts in *Tyree* and *Trevino* are unavailing as Dr. Sepulveda-Toro has not participated in the development of pelvic mesh devices nor has he authored peer-reviewed articles on the safety and efficacy of Defendants' products.[3] Put simply, Dr. Sepulveda-Toro is not qualified, nor did he utilize a reliable methodology, in forming opinions on product defects, and therefore, his opinions on this matter should be excluded.

D. Dr. Sepulveda-Toro Should Not be Permitted to Opine on Explants.

Defendants admit that Dr. Sepulveda-Toro is not a pathologist, but point to his experience in cadaver labs performing dissections as a basis for his opinions on explants and Plaintiffs' experts' pathological opinions. Critically, Defendants draw no link between experience with cadaver dissections and Dr. Sepulveda-Toro's opinions on explants and

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non-mesh surgery. However, all of these observations by Defendants are inapposite to the question before the Court, *i.e.*, they do not address the fact that Dr. Sepulveda-Toro has never drafted an IFU, never been involved in drafting an IFU, and has not even looked at the IFU for the TVT-O in six years. Pls.' Mot. at 7-8. As such, Dr. Sepulveda-Toro is not qualified to opine on Defendants' IFUs or related patient brochures.

[3] Moreover, Defendants' assertion that Dr. Sepulveda-Toro has "given input to engineers on the design of the fibers used in Ethicon's mesh devices" is demonstrably incorrect. Defs.' Opp. at 16. Dr. Sepulveda-Toro testified that he has not been involved in the design of any of Defendants' mesh devices at issue in this litigation. Ex. E at 100:1-4.

pathology; indeed, they cannot because Dr. Sepulveda-Toro does not possess this knowledge through experience or training. As such, his opinions in this regard should be excluded.

E. Dr. Sepulveda-Toro Should Not be Permitted to Opine on the Number of Studies Performed on Defendants' Products or on Degradation.

In arguing that Dr. Sepulveda-Toro is qualified to opine on the general number of studies done on Defendants' products, Defendants again interpret his opinion and testimony in a way directly contrary to its plain meaning. Defendants argue Plaintiffs' characterization of Dr. Sepulveda-Toro's opinions is "overwrought" and cite to his expert reports and reliance list as evidence of the existence of these studies. Defs.' Opp. at 18. Defendants misunderstand Plaintiffs' argument. Plaintiffs argue that Dr. Sepulveda-Toro's reference to over 100 studies, and over 1,000 (with regard to SUI products), is exaggerated, prejudicial and should be excluded. When directly asked in deposition whether Dr. Sepulveda-Toro agreed that there were *not* over 100 randomized controlled trials of TVT-O, he replied: "That is correct." Ex. F at 79:6-9. Dr. Sepulveda-Toro's exaggerated opinions are meant to imply the safety and efficacy of Defendants' products, are misleading and prejudicial, lack a sound basis, and should be excluded.

With regard to degradation, Defendants' argument that Dr. Sepulveda-Toro's testimony is consistent with a theory that mesh does not degrade defies his clear statement that "we don't have that information one way or the other." Pl.'s Mot. at 11. In fact, Defendants' quoted testimony from Dr. Sepulveda-Toro that "degradation has not been defined in a reproducible scientific way," Def.'s Opp. at 19, is entirely consistent with Plaintiffs' argument. Moreover, Defendants' various citations to prior cases in which experts have been allowed to testify on how products react within the body are inapposite as in this case, Dr. Sepulveda-Toro directly admits

there is insufficient data to opine on degradation "one way or the other." As such, Dr. Sepulveda-Toro's testimony should be excluded in this regard.

F. Defendants' Assurance that Dr. Sepulveda-Toro Will Not Use the Term "Gold Standard" is Likely Sufficient to Moot Plaintiffs' Argument.

Defendants assert that Plaintiffs' argument regarding the use of the term "gold standard" is moot as Dr. Sepulveda-Toro will instead use the term "clinical standard." Defendants are correct insofar as Dr. Sepulveda-Toro does not use the term "gold standard" in his SUI Report or in trial testimony in reference to any of Defendants' SUI products.

G. Dr. Sepulveda-Toro Should Not be Permitted to Opine on Anatomical Considerations.

Defendants argue that Dr. Sepulveda-Toro possesses the requisite experience, based primarily on his participation in cadaver labs, to opine on anatomical considerations. Defendants again misunderstand Plaintiffs' argument, which takes issue with Dr. Sepulveda-Toro's opinion that "anatomical considerations were well documented during the description and design of TVTO." Pls.' Mot. at 14 (underscore added). Dr. Sepulveda-Toro provides no basis whatsoever for this opinion; and therefore, his opinion on this matter should be excluded. Dr. Sepulveda-Toro's dissections and participation in cadaver labs have no bearing on whether anatomical considerations were well documented during the *description and design* of Defendants' products nor do Defendants provide an explanation for this purported link.

H. Dr. Sepulveda-Toro Should Not be Permitted to Opine on Whether Long Term Data on TVT and TVT-O are Inconsistent with a Theory That Mechanical Cut TVT Tape is Defective.

Again, Defendants ignore the plain meaning of Dr. Sepulveda-Toro's expert report and deposition testimony in arguing that Dr. Sepulveda-Toro should be allowed to opine that mechanical cut TVT tape is not defective. Defendants argue that: "Dr. Sepulveda cites and

discusses in several pages of his TVT and TVT-O report the studies and literature supporting his opinion," Defs.' Opp. at 21; however, this assertion is simply incorrect. Dr. Sepulveda does in fact indicate he relied upon "internal documents from Ethicon," Defs' Opp. at 21 n.8, but these internal company documents are not studies or scientific literature. In fact, Dr. Sepulveda-Toro admitted in deposition that "there has been no actual clinical studies to my knowledge [regarding the difference between laser cut and mechanical cut tape]," and as such, Dr. Sepulveda-Toro has no sufficient basis to testify that the "long term data on TVT and TVTO are also inconsistent with a theory that mechanical cut tape is defective." Pl.'s Mot. at 15 (underscore added). Thus, Defendants' argument that "[p]laintiffs' insistence that the lack of any clinical studies comparing the differences between mechanical cut tape and laser cut tape makes Dr. Sepulveda's opinions unreliable is nonsensical" is itself, nonsensical. Dr. Sepulveda-Toro should not be permitted to opine on what the "long term data on TVT and TVTO" purportedly represent when the data *does not exist*.

Presumably, the parties will argue about Defendants' internal company documents as related to what the Defendants knew and when they knew it; however, allowing Dr. Sepulveda-Toro to testify as an expert with regard to "long term data" and whether it shows mechanical cut tape is defective or not, when that data does not exist, would be prejudicial, lacks any proper basis, and should be excluded.

I. Dr. Sepulveda Should Not be Permitted to Opine on the FDA Section 510(k) Process.

Defendants argue that Dr. Sepulveda-Toro does not "misunderstand" the Section 510(k) process. Defs.' Opp. at 23. However, Dr. Sepulveda-Toro, in his SUI Report, clearly attempts to link the products' safety with the Section 510(k) process: "The host graft interaction has been previously submitted to the FDA; the tolerability and safety has been proven by the predicate

device." Pls.' Mot. at 17. As argued in Plaintiffs' Motion, the Section 510(k) process focuses on equivalence not safety, and therefore, Dr. Sepulveda-Toro not only misunderstands the Section 510(k) process, but seeks to offer testimony that would be prejudicial and confusing to the jury as the jury may also equate FDA Section 510(k) approval with safety rather than equivalence.

Defendants assert that "Dr. Sepulveda does not intend to offer any opinion on the Section 510(k) process that is inconsistent with this Court's prior rulings . . . ." Defs.' Opp. at 23. To the extent that Dr. Sepulveda-Toro will not equate Section 510(k) approval with safety, then Defendants' assertion may be adequate; however, Dr. Sepulveda-Toro's expert report clearly states otherwise, and therefore, these opinions should be explicitly excluded. Moreover, Defendants state that Dr. Sepulveda-Toro will rely upon his clinical experience and the scientific literature to opine that: "TVT is safe and effective." Defs.' Opp. at 23. As argued in Plaintiffs' Motion and herein at Section II(A) *supra*, Dr. Sepulveda-Toro should not be permitted to opine on the safety or efficacy of Defendants' products.

III. CONCLUSION

For the foregoing reasons and the reasons contained in Plaintiffs' Motion, Plaintiffs respectfully request their Motion be granted in its entirety.

Dated: May 16, 2016

Respectfully submitted,

By: /s/ Aimee H. Wagstaff
Aimee H. Wagstaff (CO Bar No. 36819)
John R. Crone (CO Bar No. 48284)
ANDRUS WAGSTAFF, P.C.
7171 W. Alaska Dr.
Lakewood, CO 80226
Telephone: (720) 208-9403
Fax Phone: (303) 376-6361
Aimee.Wagstaff@AndrusWagstaff.com

/s/ Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esq.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
Tel: (816) 701-1102
Fax: (816) 531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, FL 32563
Tel: (850) 202-1010
Fax: (850) 916-7449
rbaggett@awkolaw.com
baylstock@awkolaw.com

Counsel for Plaintiffs in MDL No. 2327

CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, a true and correct copy of *Reply to Defendants' Opposition to Plaintiffs' Motion to Limit the Opinions and Testimony of Jaime L. Sepulveda, M.D.* was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

Dated: May 16, 2016

/s/ Aimee H. Wagstaff